High-degree atrioventricular block in patients with preexisting bundle branch block or bundle branch block occurring during transcatheter aortic valve implantation

Florian Egger, MD,[*] Michael Nürnberg, MD,[*] Miklos Rohla, MD,[*] Thomas W. Weiss, MD, PhD,[*] Gerhard Unger, MD,[*] Peter Smetana, MD, PhD,[*] Alexander Geppert, MD,[*] Susanne C. Gruber, MD,[*] Anton Bambazek, MD,[†] Jürgen Falkensammer, MD,[‡] Ferdinand R. Waldenberger, MD, PhD,[§] Kurt Huber, MD, FACC,[*] Matthias K. Freynhofer, MD[*]

From the [*]3rd Medical Department, Cardiology and Emergency Medicine, Wilhelminenhospital, Vienna, Austria, [†]Department of Anaesthesiology, Wilhelminenhospital, Vienna, Austria, [‡]Department of Vascular and Endovascular Surgery, Wilhelminenhospital, Vienna, Austria and [§]Department of Cardiovascular Surgery, Hospital Hietzing, Vienna, Austria.

BACKGROUND Transcatheter aortic valve implantation (TAVI) has become the standard therapy for high-risk and non-operable patients with severe aortic stenosis. However, the procedure involves several adverse effects, such as rhythm and conduction disturbances. Patients with postprocedural left bundle branch block may have an increased mortality risk, whereas patients with preprocedural right bundle branch block display a higher rate of postinterventional bradyarrhythmias.

OBJECTIVE The purpose of this study was to investigate the occurrence of high-degree atrioventricular block (AVB) in patients with preexisting bundle branch block (BBB) or BBB occurring during TAVI.

METHODS In this prospective single-center study, 50 consecutive patients undergoing TAVI with the Medtronic CoreValve Revalving System were included. Of these patients, 17 with preexisting BBB or BBB occurring during TAVI received a primary prophylactic permanent DDD pacemaker, programmed to the SafeR-mode and featuring dual-channel event counters as well as stored intracardiac electrograms. Pacemaker readouts and intracardiac electrograms were analyzed for the occurrence of high-degree AVB.

RESULTS Ten of 17 patients (58.8%) with preexisting BBB or BBB occurring during TAVI developed episodes of high-degree AVB that were immediately terminated due to switch into DDD backup pacing. In 5 of the cases (29.4%), the first documented episode of high-degree AVB occurred after hospital discharge. Mean follow-up period was 578.1 ± 294.9 days.

CONCLUSION Development of high-degree AVB is a common complication in patients with preexisting BBB or BBB occurring during TAVI. Accordingly, intensified monitoring might be reasonable, especially in patients treated with the self-expandable Medtronic CoreValve Revalving System.

KEYWORDS Transcatheter aortic valve implantation; Pacemaker; Bundle branch block; Atrioventricular block

ABBREVIATIONS **AS** = aortic stenosis; **AV** = atrioventricular; **AVB** = atrioventricular block; **BARC** = Bleeding Academic Research Consortium; **BBB** = bundle branch block; **EGM** = electrogram; **EuroSCORE** = European System for Cardiac Operative Risk Evaluation Score; **LAFB** = left anterior fascicular block; **LBBB** = left bundle branch block; **PM** = pacemaker; **TAVI** = transcatheter aortic valve implantation; **VARC** = Vascular Academic Research Consortium

(Heart Rhythm 2014;11:2176–2182)

Introduction

Transcatheter aortic valve implantation (TAVI) is a procedure being increasingly offered to high-risk nonoperable patients with severe aortic stenosis (AS).[1] TAVI has enabled access to aortic valve replacement for patients who until now have not been accepted for surgery because of the high perioperative risk. Despite the benefits, this procedure involves several undesirable side effects, such as stroke, vascular access site complications, and acute kidney injury.[2,3]

Drs. Egger and Nürnberg contributed equally to this work. This work was supported by the Association for the Promotion of Research in Atherosclerosis, Thrombosis and Vascular Biology and by the Ludwig Boltzmann Foundation for Cardiovascular Research. Dr. Michael Nürnberg reports personal fees from Medtronic, Biotronik, Open Access Fees were funded by Sorin Group. Boston Scientific, St. Jude Medical, and Sorin outside the submitted work. Dr. Weiss reports lecture fees from Medtronic outside the submitted work. **Address reprint requests and correspondence:** Dr. Florian Egger, 3rd Medical Department, Cardiology and Emergency Medicine, Wilhelminenhospital, Montleartstrasse 37, A-1160, Vienna, Austria. E-mail address: florian_egger@gmx.net.

Among the patients treated with the self-expandable Medtronic CoreValve Revalving System, some of the most frequent complications are rhythm and conduction disturbances.[4,5] As a consequence, permanent pacemaker (PM) implantation is performed, with reported rates between 18% and 49%.[6–8] According to the current ACC/AHA/HRS guidelines, permanent PM implantation is only recommended in cases of symptomatic and/or high-degree AVB.[9] Except for these established indications, there is no generally accepted strategy for PM implantation in patients with preexisting or periprocedurally acquired conduction disturbances. However, recent publications show that new-onset left bundle branch block (LBBB) especially but also QRS prolongation in general are important and independent risk factors for all-cause mortality after TAVI.[10,11] Moreover, patients with preexisting right bundle branch block have an increased risk for the occurrence of postprocedural bradyarrhythmia and episodes of high-degree AVB necessitating permanent PM implantation.[12,13]

Cardiac asynchrony, which has been thoroughly investigated in animal models and in patients with heart failure, could be responsible for the negative influence of QRS prolongation on survival.[10,14–16] In addition, the occurrence of high-degree AVB might have a negative impact on the outcome of these patients. Conduction abnormalities occurring in the context of TAVI procedures are conceivably caused by mechanical trauma of the cardiac conduction system. Recent data show a distinct correlation between positioning of the valve prosthesis and the prevalence of LBBB.[17,18] However, a "progression" from bundle branch block (BBB) to high-degree AVB has not yet been examined. Therefore, we investigated the incidence of high-degree AVB (type 2 second-degree AVB and complete AVB) in patients with preexisting BBB or BBB occurring during TAVI.

Methods

Patient population

Between August 2010 and December 2012, 50 consecutive patients undergoing TAVI were prospectively investigated at our department. Inclusion criteria comprised an aortic valve area of $\leq 1 cm^2$ or $\leq 0.6 cm^2/m^2$ or/and a transvalvular gradient ≥ 40 mm Hg. Each patient was evaluated for TAVI by a local heart team consisting of interventional cardiologists and cardiac surgeons. Surgical risk stratification was performed using the logistic European system for cardiac operative risk evaluation score (EuroSCORE). In case of high risk or inoperability, TAVI was the offered treatment. Baseline and procedural parameters were collected for all patients. Furthermore, intracardiac electrograms (EGMs) were performed in patients with preexisting BBB or BBB occurring during TAVI and prophylactic permanent PM implantation. Patients with a preexisting permanent PM or permanent atrial fibrillation were excluded from this analysis because it was not possible to assess intracardiac EGM recordings of AVB episodes in this setting. The study was conducted in accordance with the Declaration of Helsinki and the local ethics review committee.

Procedure

Implantation of the bioprosthesis was performed in a routine manner as described elsewhere.[19] In brief, all patients received the self-expanding third-generation CoreValve Revalving System (Medtronic, Minneapolis, MN), which consists of a trileaflet porcine pericardial valve attached to a nitinol stent frame. The bioprosthesis was used in sizes of 26, 29, and 31 mm and was implanted exclusively through the transfemoral route under general anesthesia after surgical preparation of the femoral artery. Outcome parameters were assessed in accordance with the Valve Academic Research Consortium (VARC) criteria.

Superficial ECGs and intracardiac EGMs

A baseline 12-lead ECG was collected before TAVI or before prophylactic PM implantation. Rhythm, heart rate, and PR, QRS, and corrected PQ intervals were measured. Periprocedural rhythm and conduction disturbances were monitored by permanent 3-lead ECG surveillance followed by continuous rhythm monitoring for 48 hours after the intervention. All patients received a temporary right ventricular pacemaker that was removed if conduction disorders were absent 48 hours after the implantation. If episodes of high-degree AVB were detected, permanent PM implantation was performed. According to our standard operating procedures, a permanent PM (Sorin Reply/Symphony with AVB documentation in AIDA memories, Milano, Italy) was also implanted in case of preexisting BBB or BBB occurring during TAVI. All procedures were conducted under local anesthesia and dual antiplatelet therapy if performed after TAVI. The devices were programmed in the SafeR-mode, which allows intrinsic conduction and switch to DDD mode in the event of atrioventricular (AV) conduction disturbances (first- and second-degree AVB, complete AVB, and pauses >2 seconds). The unique feature of stored intracardiac EGMs of AV conduction disturbances was the main reason to implant such devices. AIDA software facilitated the documentation and analysis of stored intracardiac EGMs and allowed continuous monitoring of AV conduction.[20] In case of ventricular pacing rates below 1%, the PM software displays "$<1\%$." For calculation purposes, these values were counted as 0.9%. Two senior cardiologists (MN, PS) reviewed all ECGs and intracardiac EGMs, in order to discriminate between true high-degree AV conduction abnormalities and incidents erroneously recorded by the PM software. ECG changes were reported in accordance with the AHA/ACCF/HRS recommendations for the standardization and interpretation of the ECG.[21]

Follow-up

After an initial PM checkup within 3 months of implantation, routine follow-up visits were scheduled at least annually at our outpatient ward. At every follow-up visit, outcome and

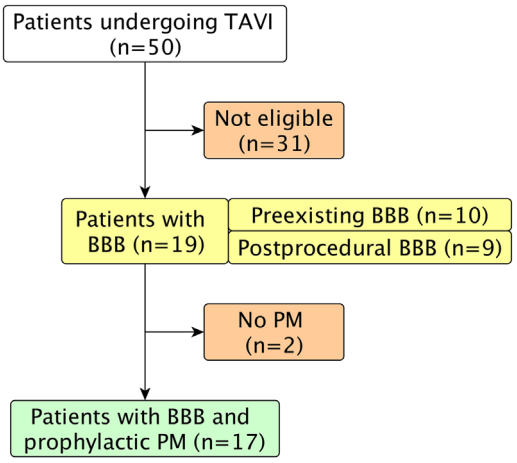

Figure 1 Study population. Categorization made using baseline and postprocedural ECG characteristics. BBB = bundle branch block; PM = pacemaker; TAVI = transcatheter aortic valve implantation.

end-point data were assessed. All patients were referred for pacemaker checkup and transthoracic echocardiography. Clinical, functional, and biochemical parameters were collected. Rhythm and conduction disturbances were evaluated with 12-lead ECG records and readouts of AVB documentation in AIDA memories.

Statistical analysis

Categorical variables are reported as frequency count and percentage. Differences between groups were investigated using the χ^2 or Fisher exact test, as required. Continuous variables are reported as mean with SD or as median with interquartile range. Normal distribution was confirmed by the Shapiro–Wilk test. Groups were compared by the Wilcoxon–Mann–Whitney test or *t* test, whichever was appropriate. Significance was assumed in case of 2-sided $P \leq .05$. Statistical analysis was conducted using SPSS 20 (IBM Corp, Armonk, NY).

Results

Study population

Of the 50 patients who were treated with TAVI, 31 patients were not eligible for the following reasons: 20 either presented with permanent atrial fibrillation or already had a permanent PM implanted; 2 patients died periprocedurally; 4 patients showed unimpaired conduction; 1 patient showed left anterior fascicular block (LAFB) before and after the intervention; and therapeutic permanent PM implantation was necessary in 3 patients with normal conduction and in 1 patient with LAFB at baseline but complete AVB after the procedure.

In 19 patients, preexisting BBB or BBB occurring during TAVI was present. One of these patients died before a permanent PM could be implanted. A second patient did not receive a permanent PM at the discretion of the interventionalist. The remaining 17 patients with a documented preexisting BBB or BBB occurring during TAVI had a prophylactic permanent PM implanted and were eligible for assessment of rhythm and conduction disturbances. The study population is depicted in Figure 1. Details on preexisting and postprocedural new-onset conduction disturbances are shown in Figure 2. Table 1 gives the baseline characteristics of the whole patient collective and of the patients with prophylactic permanent PM implantation, respectively.

TAVI procedure and PM implantation

Valve dimensions of 26, 29, and 31 mm were used in 32, 17, and 1 case, respectively. Acute procedural success rate was 94.0% (n = 47). Immediate procedural mortality (death within 72 hours of TAVI) was 4.0% (n = 2): 1 patient died due to rupture of the aortic annulus after balloon

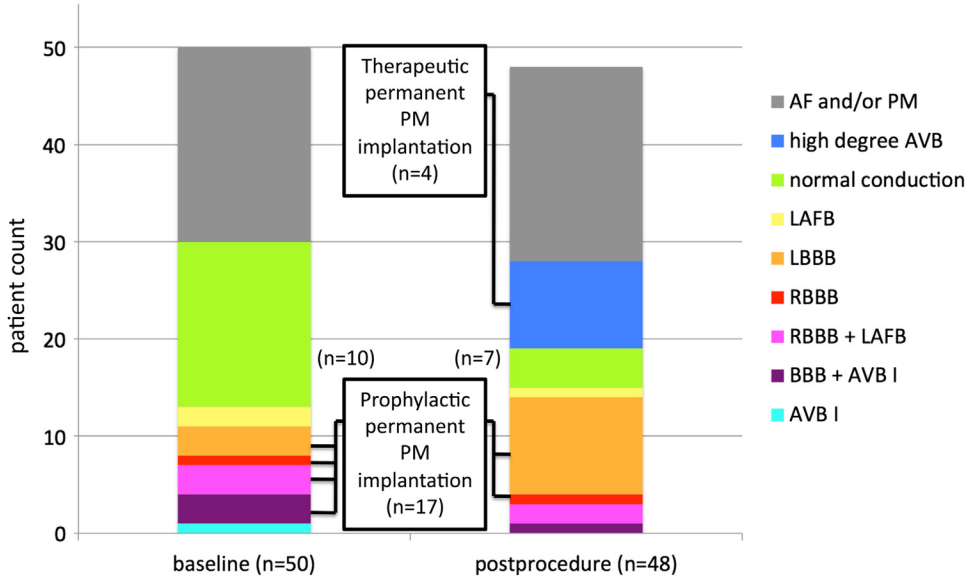

Figure 2 Details of preexisting and postprocedural new-onset conduction abnormalities. AF = atrial fibrillation; AVB = atrioventricular block; AVB I = first-degree atrioventricular block; BBB = bundle branch block; LAFB = left anterior fascicular block; LBBB = left bundle branch block; PM = pacemaker; RBBB = right bundle branch block.

Table 1 Baseline characteristics of the whole study population and patients with prophylactic permanent PM implantation

	All patients (n=50)	Prophylactic PM (n=17)
Clinical paramenters		
Age (years)	84.0 (78.8–87.0)	83.0 (80.0–85.5)
Gender (male)	16 (32.0%)	4 (23.5%)
Aortic valve area (cm^2)	0.7 (0.6–0.9)	0.7 (0.6–0.9)
NYHA level		
1	0 (0.0%)	0 (0.0%)
2	7 (14.0%)	3 (17.6%)
3	39 (78.0%)	14 (82.4%)
4	4 (8.0%)	0 (0.0%)
Logistic EuroSCORE	25.6 (±13.2)	25.8 (±14.5)
Atrial fibrillation	16 (32.0%)	
Preexisting pacemaker	11 (22.0%)	
Interventional parameters		
Acute procedural success	47 (94.0%)	17 (100%)
30-day survival	46 (92.0%)	17 (100%)
Days in ICU	2.0 (2.0–5.0)	3.0 (2.0–6-0)
Days on ward	10.0 (7.0–14.8)	8.0 (6.5–13.5)
Days in hospital	13.0 (10.0–19.0)	13.0 (9.5–15.0)
Time (hh:mm)	02:57 (±0:53)	02:41 (±0:38)
Prosthesis size		
26 mm	32 (64.0%)	13 (76.5%)
29 urn	17 (34.0%)	3 (17.6%)
31 mm	1 (2.0%)	1 (5.9%)

ICU = intensive care unit; NYHA = New York Heart Association; PM = pacemaker.

valvuloplasty, and 1 patient died of left ventricular perforation with pericardial tamponade. The implantation of 2 valves was necessary once, after 1 bioprosthesis had dislocated into the aortic arch. After an initial improvement of the medical condition, uncontrollable systemic inflammatory response syndrome resulted in death after the third postprocedural day. One-month survival was 92.0% (n = 46).

In 10 patients with preexisting BBB, a permanent PM was implanted 11.4 ± 11.6 days before TAVI. In another 9 patients, BBB occurred during TAVI. Permanent PM implantation was performed in 7 of these patients 2.3 ± 1.2 days after the intervention. PM lead revision was necessary once because of dislocation of the atrial lead. Moreover, 4 patients experienced postoperative hematoma, which were classified as type 1 bleedings according to the Bleeding Academic Research Consortium (BARC) classification.[22] Inflammatory markers were temporarily elevated in 1 patient. No further complications were documented. One of the patients, who died within 30 days after TAVI, had developed new-onset LBBB immediately after the procedure. Permanent PM implantation was scheduled but postponed because of rising C-reactive protein levels. Fifteen days after the intervention, the patient syncopated and eventually died of intracranial hemorrhage.

AV conduction abnormalities

Altogether, 10 of 17 patients (58.8%) with preexisting BBB or BBB occurring during TAVI and subsequent prophylactic permanent PM implantation developed true (electronically stored) episodes of high-degree AVB. In 5 of these patients (29.4%), the first documented episode occurred after hospital discharge (Figure 3). None of these 5 patients was pacemaker dependent at the subsequent routine clinical visit or hospital admission (Table 2). The ventricular pacing rate of patient subgroups during follow-up is depicted in Figure 4.

One patient who had a documented episode of high-degree AVB 47 days after hospital discharge showed entire resolution of the LBBB, occurring during TAVI, 5 days after the intervention. Other than this specific case, all other intraventricular conduction abnormalities (preexisting BBB or BBB occurring during TAVI) persisted until the end of follow-up.

Software-based event adjudication

Altogether, intracardiac EGMs of 124 events were recorded and classified as second-degree AVB, complete AVB, or pause by the PM software. Only 44.4% of these stored episodes proved to be true high-degree AVB. According to automated event adjudication, 88.2% (n = 15) of patients with prophylactic PM implantation suffered from episodes of high-degree AVB. After diligent validation of every documented episode, this diagnosis was only correct in 58.8% (n = 10) of the patients. Common underlying abnormalities were paroxysmal atrial tachycardia with physiologic type 1 second-degree AVB, ventricular undersensing, or ventricular sensing during atrial blanking, respectively.

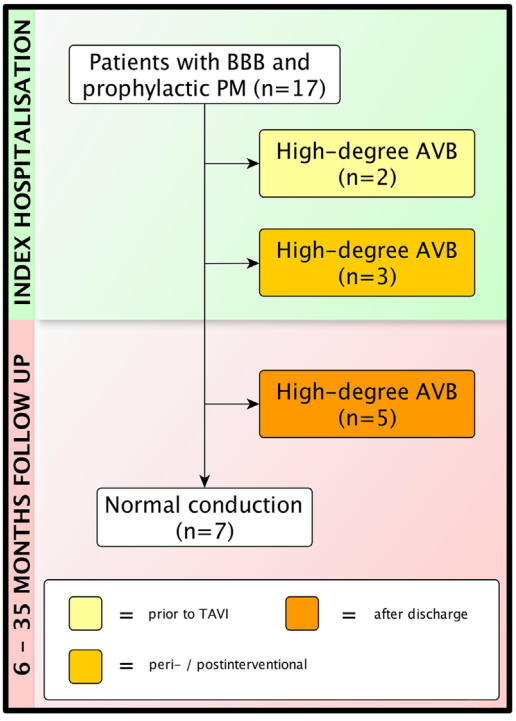

Figure 3 Patient flow through the study. Background colors indicate the time of events and the setting of patients. AVB = atrioventricular block; BBB = bundle branch block, PM = pacemaker; TAVI = transcatheter aortic valve implantation.

Table 2 Rhythm and cardiac conduction and occurrence of high-degree AV conduction disturbances

			12-Lead ECG Prior to TAVI		12-Lead ECG After TAVI		Stored EGM during follow-up		
Cons. Nr.	Pat. Nr.	Permanent PM	Rhythm	Conduction	Rhythm	Conduction	High-degree AVB	Onset	Interval (days)
1	1	After TAVI	SR	Normal	SR	LBBB	no		
2	3	After TAVI	SR	Normal	SR	LBBB	yes	After discharge	427
3	5	Prior to TAVI	SR	RBBB+LAFB+AVB 1	SR	high-degree AVB	yes	Before discharge	
4	7	Prior to TAVI	SR	RBBB+LAFB	SR	high-degree AVB	yes	Before discharge	
5	8	After TAVI	SR	Normal	SR	LBBB	no		
6	10	Prior to TAVI	SR	LBBB	SR	LBBB	yes	Before TAVI	
7	12	After TAVI	SR	Normal	SR	L8BB	no		
8	15	After TAVI	SR	Normal	SR	LBBB	no		
9	18	Prior to TAVI	SR	LBBB	SR	LBBB	yes	Before TAVI	
10	24	Prior to TAVI	SR	LBBB+AVB 1	SR	LBBB	yes	After discharge	730
11	26	Prior to TAVI	SR	RBBB+LAFB	SR	RBBB+LAFB	no		
12	29	After TAVI	SR	Normal	SR	RBBB	yes	After discharge	235
13	31	Prior to TAVI	SR	LBBB	SR	LBBB	no		
14	42	Prior to TAVI	SR	RBBB	SR	High-degree AVB	yes	Before discbarge	
15	44	After TAVI	SR	LBBB+AVB 1	SR	LBBB+AVB 1	no		
16	45	Prior to TAVI	SR	RBBB+LAFB	SR	RBBB+LAFB+AVB 1	yes	After discharge	64
17	47	After TAVI	SR	Normal	SR	LBBB	yes	After discharge	47

AVB 1 = first-degree atrioventricular block; Cons. Nr. = consecutive number; EGM = electrogram; Interval = days between hospital discharge and first document episode of high-degree atrioventricular block; LAFB = left anterior fascicular block; LBBB = left bundle branch block; Pat. Nr. = patient number; PM = pacemaker; RBBB= right bundle branch block; SR = sinus rhythm TAVI = transcatheter aortic valve implanation.

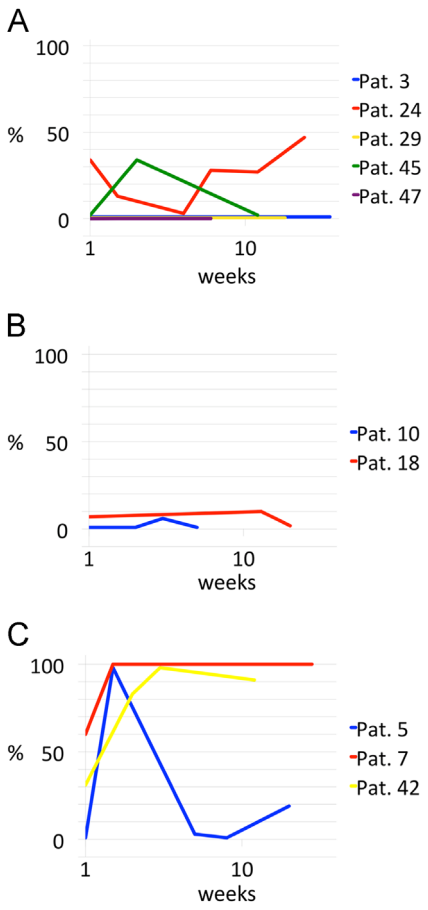

Figure 4 Ventricular pacing rate (VPR) of patient subgroups depicted on a logarithmic timeline. **A:** VPR of patients with high-degree atrioventricular block (AVB) after discharge. **B:** VPR of patients with high-degree AVB before transcatheter aortic valve implantation. **C:** VPR of patients with periprocedural/postprocedural high-degree AVB. Pat. = patient.

Discussion

The main finding of the present study is that 58.8% of patients with preexisting BBB or BBB occurring during TAVI with the Medtronic CoreValve Revalving System developed episodes of high-degree AVB. Most importantly, half of these high-degree AVB episodes initially occurred after hospital discharge. To the best of our knowledge, this is the first study using continuous intracardiac EGM-based event recording to investigate the frequency of high-degree AVB in patients with preexisting BBB or BBB occurring during TAVI.

Conduction disturbances after TAVI

The occurrence of BBB and AVB after TAVI has been demonstrated in various trials and registries.[2,3,5] Continuous radial force, as well as transient tissue inflammation, edema, and ischemia, have been suggested as possible reasons for these partly transient conduction abnormalities.[6,23] Urena et al[18] reported a significantly increased rate of permanent PM implantations due to high-degree AVB in patients with postprocedural new-onset LBBB compared to those without conduction abnormalities. Contradictory data concerning the impact on prognosis of BBB occurring during TAVI have been reported.[10,17,18] Some evidence indicates that preoperative or postoperative BBB in patients with surgical aortic valve replacement is associated with an increased adverse event rate.[24] Accordingly, because of the potential severe sequelae associated with impaired AV conduction, prophylactic permanent PM implantation has been suggested for surgically treated patients.[24] Houthuizen et al[10] reported similar findings for patients with LBBB induced by TAVI. Besides a 2-fold increase of cardiovascular mortality, the absolute and relative mortality risk were elevated. Moreover,

LBBB complicating TAVI turned out to be the strongest independent predictor of all-cause mortality. Explanations include interventricular and intraventricular asynchrony due to altered ventricular activation or the onset of rhythm and conduction abnormalities, as already described for patients suffering from myocardial infarction aggravated by LBBB.[14,15,25–27]

In our study cohort, episodes of high-degree AVB were observed in patients with preexisting BBB or BBB occurring during TAVI. Two of the patients with preexisting BBB developed high-degree AVB after permanent PM implantation but before TAVI. Because the range of symptoms of high-degree AS and AVB overlap, it is a debatable point whether transient episodes of high-degree AVB would have been detected before hospital discharge without prophylactic permanent PM implantation. These findings underline the vulnerability of the cardiac conduction system and raise the question whether an extension of postinterventional monitoring might be reasonable in selected patients. Furthermore, the periprocedural measurement of electrophysiologic parameters might help to stratify patients according to their risk for the development of AV conduction abnormalities.

In the absence of contraindications, temporary pacemaker leads are commonly removed 48 to 72 hours after the procedure, followed by a period of telemetric monitoring for several days. With regard to episodes of new-onset high-degree AVB detected after hospital discharge, the available literature is inconsistent. The need for late permanent PM implantation because of conduction abnormalities occurring after hospital discharge has been reported repeatedly.[18,28,29] In a survey of 65 patients conducted by Pereira et al,[30] permanent PM implantation after hospital discharge was not necessary. Moreover, a decline in pacemaker dependency over time was recently demonstrated by Simms et al.[31] Transient episodes of high-degree AVB may not be detected safely by means of 12-lead ECG documentation at routine follow-up visits.

Study limitations

The use of certain PM devices allows continuous event recording and enables *post hoc* assessment of documented events. However, the memory storage volume of the respective PM is limited to the last 8 AVB episodes occurring before pacemaker checkup. If patients die before a pacemaker memory recall can be performed, data are irretrievably lost. Accordingly, our results may even underestimate the actual prevalence of high-degree AV conduction abnormalities in such patients. The major limitation of the present data is the small sample size. Our results are hypothesis-generating and require confirmation in larger patient cohorts. Furthermore, no data are available about the frequency of conduction abnormalities in patients without BBB.

The clinical relevance of our findings can only be hypothesized because the PM instantaneously switches to DDD mode in case of high-degree AVB. Thus, we are not able to draw conclusions regarding the influence of these episodes on clinical outcome and quality of life.

Another limitation is that the implantation depth of the bioprosthesis was not measured in our study. However, optimal positioning of the stent frame was aspired for every single patient in order to avoid impairment of the cardiac conduction system. Because all patients received the self-expandable Medtronic CoreValve Revalving System, it is not possible to extrapolate results to patients treated with other devices.

Conclusion

Patients with preexisting BBB or BBB occurring during TAVI are at risk for the development of high-degree AVB. Accordingly, intensified monitoring might be reasonable, especially in patients treated with the self-expandable Medtronic CoreValve Revalving System. Further prospective trials in greater numbers of patients are required to confirm our findings and determine the clinical need for prophylactic permanent PM implantation.

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CLINICAL PERSPECTIVES

High-degree atrioventricular block ranks among the most common complications, especially in patients undergoing transcatheter aortic valve implantation with the self-expandable Medtronic CoreValve Revalving System. According to previous investigations, the majority of atrioventricular conduction abnormalities occurs during the intervention or shortly thereafter. However, several authors have reported the need for delayed permanent pacemaker implantation because of the late occurrence of high-degree atrioventricular block.

In the present study, we discovered a high incidence of high-degree atrioventricular bock episodes in patients with preexisting or postprocedural new-onset intraventricular conduction abnormalities. Because of continuous monitoring by means of intracardiac electrograms, we were able to detect episodes of high-degree atrioventricular block in patients who would have been discharged without permanent pacemaker implantation according to currently available recommendations.

Therefore, intensified monitoring might be reasonable at least for selected patients treated with the self-expandable Medtronic CoreValve Revalving System. Furthermore, an electrophysiologic workup comparable to that recommended for patients with bundle branch block and syncope might help to identify patients who presumably might benefit from permanent pacemaker implantation.